



USDA Foreign Agricultural Service

# GAIN Report

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## Japan

### Food Processing Ingredients Sector

### MHLW Requires Irradiation Statement for Health Food Ingredients

**2007**

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**Report Highlights:**

On September 19, 2007, Japan's Ministry of Health, Labor, and Welfare (MHLW) notified its port inspectors that imports of U.S. dry or powdered "agricultural products" intended for use in "health foods" need to carry documentation from the manufacturer stating that the product has not been irradiated. According to Japanese officials, the requirements are in response to a recent voluntary recall of fermented soy ingredients used in health foods. The manufacturer of the soy ingredients (isoflavones) was suspected to have used irradiation as a preservation method. The new requirements target U.S. products only. The measures have not been notified to the WTO nor have Japanese officials identified the health risks that are being addressed. Companies experiencing delayed or detained shipments are requested to contact [agtokyo@usda.gov](mailto:agtokyo@usda.gov).

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Annual Report  
Tokyo [JA1]  
[JA]

On September 19, 2007, Japan's Ministry of Health, Labor, and Welfare (MHLW) notified quarantine authorities that imports of U.S. dry or powdered "agricultural products" intended for use in "health foods" must be accompanied by documentation from the manufacturer stating that the product has not been irradiated.

According to Japanese officials, the requirements are in response to a recent voluntary recall of fermented soy extract products that had been imported into Japan. These materials, which are common ingredients in health food products, were suspected to have been irradiated. Japan currently prohibits the sale of both irradiated food and food with irradiated ingredients (please also see [JA6061](#)).

In its notification (translation below), MHLW uses vague terms such as "agricultural products" in dry or powdered form including grains, fruits, and vegetables. Another broad term, "health foods", is reportedly intended to include items such as supplements but regular foods. Japanese officials have stated that the requirements are intended only apply to imports of products for which irradiation treatment may be used in the United States; however, there is a lack of specificity in the definitions used and scope of the requirements.

Documentation to meet the requirement can reportedly be provided by the manufacturer of the product rather than by third party certification. Japanese officials have indicated that importers can put the statement on the standard import documentation in the section referring to manufacturing processes.

As of this time, Japan has not notified the measure to the WTO or allowed for a public comment period.

FAS/Tokyo would appreciate feedback from companies affected by the new requirement, especially in instances where the new measure results in a detained or delayed shipment. Comments can be addressed to [agtokyo@usda.gov](mailto:agtokyo@usda.gov).

The following is an unofficial Embassy translation of MHLW's order to Japanese quarantine officials.

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(Provisional translation)  
#0919004

September 19, 2007

Dear Director of Quarantine Office

Imported Food Safety and  
Inspection Division, MHLW

Regarding confirmation of the sterilization method for food and other materials from the  
United States

The issue in the title is implemented by Imported Foods Monitoring and Guidance Plan for FY 2007 (<http://www.mhlw.go.jp/topics/yunyu/dl/tp0130-1z.pdf>), and the official announcement at June 10, 2005 (#0610002), the Office Memo at October 30, 2006, and the official announcement at June 1, 2007 (#0601001).

Recently, fermented soy extract products imported as a raw material for health food products were voluntarily recalled by the importer because it was suspected that the raw materials were irradiated. Per our inquiry to the U.S. Government, we confirmed that the fermented soy extract products would be classified as a type of dried vegetables used as raw material for condiments and spices that is allowed to be irradiated.

Hereafter, we request that you confirm that each shipment of dried and powered agricultural products from the United States being used as raw material for health foods is documented by in a letter by the manufacture stating to the importer that the product is not irradiated.